In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-57V
Filed: July 12, 2022
PUBLISHED

BECKY LAYNE,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Shoulder Injury Related to Vaccine Administration ("SIRVA"); Influenza ("Flu") Vaccine; Ruling on the Record

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for petitioner.
Jamica M. Littles, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On January 11, 2018, petitioner, Becky Layne, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that her receipt of an influenza vaccination on November 2, 2016, caused a left shoulder injury. (ECF Nos. 1, 30.)[3] For the reasons set forth below, I conclude that petitioner is entitled to an award of compensation.

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

[3] Petitioner's original petition alleges "*left shoulder injuries* resulting from the adverse effects of the influenza vaccination…received on November 2, 2016." (ECF No. 1 (emphasis added).) While petitioner's amended petition simply alleges "*injuries* related to vaccine administration ("SIRVA") as a result of an influenza vaccination…received on November 2, 2016." (ECF No. 30 (emphasis added).) As petitioner's motion for a ruling on the record makes clear, petitioner alleges that she suffered a left-sided shoulder injury meeting all four criteria demonstrating a SIRVA Table injury, (ECF No. 49, p. 9) or

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of administration of an influenza vaccine. § 300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by statutory "Qualifications and aids in interpretation" ("QAIs"), which provides more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that his injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged

alternatively, that reliable medical evidence supports a non-Table injury that was caused-in-fact by her vaccination (*Id.* at 15).

signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time-frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR §100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To so demonstrate, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must show by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury in order to prove causation-in-fact. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005)

For both Table and Non–Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In this case, petitioner stresses that she suffered a left-sided shoulder injury meeting all four criteria demonstrating a SIRVA Table injury. (ECF No. 49, p. 9.) Alternatively, petitioner asserts that reliable medical evidence supports a non-Table injury was caused-in-fact by her vaccination. (*Id.* at 15.)

II. Procedural History

Petitioner filed her petition, affidavit, and medical records on January 11, 2018. (ECF No. 1.) This case was initially assigned to the Court's Special Processing Unit

("SPU") on January 16, 2018. (ECF Nos. 5, 6.) On January 17, 2018, petitioner filed additional medical records and a statement of completion. (ECF Nos. 7-8.) An initial status conference was held on March 1, 2018. (ECF No. 12.) Subsequently, petitioner filed a supplemental affidavit, further medical records, and an amended statement of completion. (ECF Nos. 13, 14, 17-18.)

On December 3, 2018, respondent filed his Rule 4(c) report recommending against compensation. (ECF No. 26.) Thereafter petitioner was ordered to file an amended petition clarifying the nature of her claim, any outstanding physical therapy records, and an expert report. (ECF No. 27.) On January 10, 2019, petitioner filed updated physical therapy records. (ECF No. 28.) On February 15, 2019, petitioner filed an expert report authored by Naveed Natanzi, D.O. as well as the supporting medical literature. (ECF No. 29.) Petitioner filed her amended petition on March 11, 2019. (ECF No. 30.)

On February 15, 2019, respondent filed a responsive expert report from Geoffrey Abrams, M.D., with accompanying medical literature. (ECF No. 34.) Thereafter this case was reassigned to Special Master Mindy Roth on July 2, 2019. (ECF No. 37.) On October 17, 2019, a status conference was held and petitioner was ordered to submit a reasonable settlement demand to respondent. (ECF No. 38.) After settlement negotiations were unsuccessful, petitioner elected to file to a responsive supplemental expert report from Dr. Natanzi on March 23, 2020. (ECF No. 42.)

Subsequently, the parties filed a joint status report on June 22, 2020, electing to proceed with motions for a ruling on the record. (ECF No. 44.) Concurrently, petitioner requested the opportunity to file a responsive expert report in conjunction with her motion. (*Id.*) On September 15, 2020, petitioner filed a second supplemental expert report from Dr. Natanzi, as well as an expert report authored by Tinoosh Zand, M.D., regarding petitioner's MRI arthrogram of the left shoulder. (ECF No. 47.) On October 20, 2020, petitioner filed her motion for a ruling on the record. (ECF No. 49.) On February 5, 2021, respondent filed his responsive brief. (ECF No. 51.) Petitioner filed her reply to respondent's response on February 12, 2021. (ECF No. 52.)

Subsequently, this case was reassigned to my docket on February 4, 2022. (ECF No. 55.) In light of the posture of the case upon reassignment, I issued a NON-PDF Order on February 8, 2022, advising the parties that "[a]t the time of reassignment, a ripe motion for a ruling on the written record [] remained pending" and "[a]bsent further action from the parties, I intend to act on the pending motion in due course without further proceedings." (Dkt Text 2/8/22.) On March 21, 2022, petitioner filed Dr. Natanzi's CV. (ECF No. 56.) However, neither party took any further action in response to my Order of February 8, 2022.

On May 2, 2022, I instructed petitioner to file a complete copy of Dr. Cincere's record of December 20, 2016, a request that had been made in respondent's brief.

(Sched. Order (Non-PDF), 5/2/2022 (citing ECF No. 51, p. 3, n. 1). Petitioner filed the required records on June 29, 2022. (ECF No. 58; Ex. 25.)

I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record."). Accordingly, this matter is now ripe for resolution.

III. Factual History

a. As reflected in the medical records

On November 2, 2016, petitioner received an influenza vaccination in her left arm. (Ex. 1, p. 1.) An undated handwritten note on the vaccination record states that "she had a severe reaction to the flu shot. Very sore arm (the shot site) a week later. Reported CDC." (*Id.*) Prior to this vaccination, petitioner had no history of injury to her left shoulder. (Ex. 2, pp. 18, 22-34; Ex. 11, pp. 1-12.)

On November 11, 2016, petitioner presented to her primary care provider ("PCP") Teresa Regan, D.O. (Ex. 2, p. 18.) Petitioner reported that her arm was red, swollen, and warm to the touch since receiving a flu shot on November 2nd. (*Id.*) The note states that "they told her it was a bad reaction to the Flu VACC" and the shot "was given supposedly im [intramuscular] but appears to have been given near the superior deltoid tendon." (*Id.*) Petitioner reported significant pain, significant decreased range of motion, and an audible click in the "rotator cuff area." (*Id.*) Dr. Regan noted "severe point tenderness in [the rotator cuff] region and over acj [acromioclavicular joint], short head of biceps and supraspinatus and joint capsule." (*Id.*) Additionally, petitioner reported numbness, tingling, and pain to the left hand. (*Id.*) On physical examination, Dr. Regan observed decreased range of motion with abduction and external rotation greater than internal rotation to less than 90 degrees from the horizontal plain. (Ex. 2, p. 18.) Petitioner also indicated that she "may have had some chills immediately after the injection." (*Id.*) Dr. Regan administered an injection of Ketorolac Tromethamine[4] in her right gluteus and prescribed Diclofenac[5] and Percocet.[6] (*Id.* at 20.) Dr. Regan also

[4] "a nonsteroidal anti-inflammatory drug administered intramuscularly, intravenously, or orally for short=term management of pain[.]" *Ketorolac Tromethamine,* DORLAND' MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=26960&searchterm=ketorolac%20tromethamine (last accessed Mar. 23, 2022.)

[5] "a nonsteroidal anti-inflammatory drug derived from phenylacetic acid." *Diclofenac,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=13937&searchterm=diclofenac (last accessed Mar. 23, 2022).

[6] "Trademark for a combination preparation of oxycodone hydrochloride and acetaminophen." *Percocet,* DORLAND'S MEDICAL DICTIONARY ONLINE,

ordered an ultrasound to rule out septic joint versus an injury to the left rotator cuff. (*Id.* at 18.) That same day, petitioner underwent a CT scan of her left shoulder. (Ex. 2, p. 47.) The history indicates "joint pain" and "patient reports injection complications of the flu shot." (*Id.*) The CT scan showed normal findings, including no acute fracture or evidence of osteomyelitis, no significant arthritic changes, no radiopaque foreign body, edema, inflammation, fluid collection, or appreciable glenohumeral joint effusion. (*Id.*)

A VAERS report was filed on November 18, 2016. (Ex. 1, p. 2.) On November 30, 2016, petitioner underwent an MRI of the left shoulder. (Ex. 13.) The history indicated "[l]eft shoulder pain following a flu shot in November 2016" and "[p]ain radiating into the left hand." (*Id.*) The MRI showed no evidence of a rotator cuff tear, labral injury, or occult bone injury, and no abnormality in the subcutaneous or deltoid muscles surrounding the left humerus. (*Id.*)

On December 20, 2016, petitioner presented to Brandon Cincere, M.D., an orthopedist. (Ex. 25, pp. 15-18; *see also* Ex. 14, pp. 2-3; Ex. 3, p. 2.) Petitioner reported that her therapeutic injection had not provided relief and that she "is having sharp and achey pains" as well as pain radiating to her fingers.[7] On examination petitioner's passive range of motion was "limited and guarded, improved," and empty can and full can tests were positive. (Ex. 25, p. 16.) Upon reviewing petitioner's MRI, Dr. Cincere indicated that he disagreed with the radiologist's report on the axial images. (*Id.*) Dr. Cincere's impression was left shoulder pain with "limited ROM after flu shot, no relief with IA injection, MRI with RTC tendinosis and bursitis." (*Id.* at 17.) Petitioner was diagnosed with pain, bursitis, and unspecified mononeuropathy of the left shoulder. (*Id.*) Petitioner was given a steroid injection and Dr. Cincere ordered an electromyogram ("EMG") with the note "please evaluate suprascapular nerve." (*Id.*)

On January 3, 2017, petitioner was seen at Ocoee Regional Health for musculoskeletal pain and an adverse reaction to a flu shot. (Ex. 10, pp. 1-3.) Under the heading "musculoskeletal pain," petitioner reported severe pain in her neck and shoulders that began three days earlier; she reported no injuries; and described waking up with a "crick in her neck." (*Id.*) Under the heading "adverse reaction to flu shot," petitioner reported constant, severe pain in her left shoulder that began two months prior. (*Id.*) In the review of systems, petitioner reported extremity weakness with no numbness. (*Id.*) On examination, PAC Caleb Rae noted a "right muscle spasm" and painful range of motion in the cervical spine, and moderately reduced range of motion in

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https://www.dorlandsonline.com/dorland/definition?id=37652&searchterm=Percocet (last accessed Mar. 23, 2022.)

[7] The record indicates in the narrative that this history was provided relative to the right shoulder. (Ex. 25, p. 15.) However, the record is clear in indicating petitioner was presenting with a chief complaint relative to her "left shoulder." Moreover, the record as a whole is clearly focused on petitioner's left shoulder and the resulting diagnoses all specifically relate to the left shoulder. (*Id.* at 17.) Accordingly, it appears this isolated reference to the right shoulder is an error within the record.

the left shoulder. (*Id.*) The assessment was cervicalgia and petitioner was advised to continue heating, massaging, and stretching. (*Id.*)

On January 4, 2017, petitioner returned to Dr. Regan complaining of neck and shoulder pain. (Ex. 2, p. 14.) Petitioner reported that she had started developing neck pain, worse on the left, on Sunday at dinner and it had gotten worse, radiating down her left shoulder and right shoulder. (*Id.*) She also described numbness and tingling to the 2nd, 3rd, and 4th digits of the left hand "but this is not new or worse." (*Id.*) Petitioner reported a headache in the back of the head. (*Id.*) She indicated that she received a steroid shot and Robaxin[8] at the clinic the previous day and was "getting no better but worse." (*Id.*) On examination petitioner had tenderness to palpation over the left and right paracervical areas and bilateral trapezius, as well as decreased range of motion in her neck and in all plains and tenderness of paracervical muscles. (*Id.* at 15.) Petitioner was assessed with headache and "joint pain – neck pain." (Ex. 2, pp. 15-16.) She was advised to apply moist to the neck area and to avoid taking Robaxin. (*Id.* at 17.)

On February 1, 2017, petitioner underwent an EMG which showed evidence of left suprascapular neuropathy. (Ex. 4, pp. 24-25.) The history indicates that petitioner had persistent left shoulder and left upper extremity pain and weakness; with numbness, tingling and "paresthesias in her left arm that radiated down her arm and affect digits 3 through 5." (*Id.* at 24.) On limited examination, petitioner had somewhat limited mobility in her neck and left shoulder, secondary to pain; and the right shoulder mobility was normal. (*Id.*) The impression indicates that "[t]his is an abnormal study," finding evidence of left suprascapular neuropathy, affecting both the left supraspinatus and left infraspinatus; however, there was no evidence of right suprascapular neuropathy, cervical radiculopathy, brachial plexopathy, left median neuropathy, left ulnar neuropathy, or left radial neuropathy. (*Id.*)

On February 7, 2017, petitioner returned to Dr. Cincere. (Ex. 4, pp. 26-29; Ex. 14, pp. 4-8.) Petitioner reported that the injection from her previous visit did not help much. (Ex. 4, p. 26.) She indicated that she saw her PCP and "believes she has nerve damage." (*Id.*) She described constant pain which she rated as 7/10. (*Id.*) Petitioner's left shoulder passive range of motion was 170-90-90-30-40, her empty can test was negative and full can test was positive, her infraspinatus was weak, her Hawkins and Neer's tests were positive, and her O'Brien's test was negative. (*Id.* at 28.) She was diagnosed with suprascapular nerve compression, pain in the left shoulder, incomplete rotator cuff tear/ruptured left shoulder (not traumatic), impingement syndrome and bursitis in the left shoulder, and other specified mononeuropathies in the left upper limb.

[8] "Trademark for preparation of methocarbamol." *Robaxin,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=44009&searchterm=Robaxin (last accessed Mar. 23, 2022). "a skeletal muscle relaxant, administered orally, intramuscularly, or intravenously in the treatment of painful musculoskeletal conditions." *Methocarbamol,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=30925 (last accessed Mar. 23, 2022.)

(*Id.*) The note states that an MRI showed bursal signal changes and rotator cuff signal changes. (*Id.* at 29.) Petitioner elected to undergo surgery. (*Id.*)

On February 22, 2017, petitioner underwent left shoulder surgery. (Ex. 4, pp. 21-23; Ex. 14, pp. 17-19.) Petitioner's preoperative diagnoses were: 1) left shoulder subacromial impingement bursitis; 2) left shoulder rotator cuff tendinitis; and 3) left shoulder suprascapular neuropathy. (Ex. 4, p. 21.) Petitioner's postoperative diagnoses were the same, with the addition of left humeral head chondromalacia. (*Id.*) In the findings Dr. Cincere reported

> extensive subacromial bursitis and anterolateral acromial overhanging with intact bursal-sided rotator cuff partial, small tearing of the anterior fibers of the supraspinatus articulated with an associated chondral flap injury in this area, and completely intact biceps in the groove portion and superior labrum. [Petitioner] [had] some mild fraying of the anterior labrum. Intact remaining cartilage with significant subacromial narrowing.

(*Id.* at 21-22.)

Thereafter petitioner underwent her initial physical therapy evaluation on February 23, 2017. (Ex. 5, pp. 318-22.) In the history of present condition, Ann Miller-Talent, PT, DPT, noted that petitioner "reports having an adverse reaction to a flu shot, which resulted in bursitis, nerve damage, and difficulty moving and using the LUE [left upper extremity]." (*Id.* at 318.) On examination, petitioner's left shoulder active range of motion was not tested, and her passive range of motion was 60 degrees flexion, 35 degrees abduction, 10 degrees external rotation in neutral position, and 50 degrees in internal rotation in neutral position. (*Id.* at 319.) In her assessment, DPT Miller-Talent noted that petitioner presented with "signs and symptoms consistent with status post arthroscopic repair." (*Id.* at 320.) She further observed decreased range of motion, decreased strength, swelling, and pain. (*Id.*) Thereafter petitioner attended sixty-five sessions of physical therapy through December 8, 2017. (*See* Ex. 5.)

Petitioner presented to Dr. Cincere for a follow-up on March 3, 2017. (Ex. 4, pp. 31-33; Ex. 14, pp. 9-11.) She described a constant pain for the past nine days in the side and top of her shoulder that also "radiates to the arm," which she rated as a 7/10. (Ex. 4, p. 31.) Her "status [wa]s reported as improving." (*Id.*) On examination petitioner's left shoulder range of motion was limited and painful. (*Id.* at 32.) She returned to see Dr. Cincere again on April 6, 2017. (Ex. 4, pp. 35-37; Ex. 14, pp. 13-15.) Petitioner was taking Vimovo and stated that it was helping. (Ex. 4, p. 35.) Petitioner described constant, "sharp, stabbing, radiating and throbbing" shoulder pain for four months. (*Id.*) The pain "radiates to the shoulder, fingers, and hand." (*Id.*) She rated the pain as 6/10. (*Id.*) On examination, petitioner's left shoulder passive range of motion was 150-90-80-10-30. (*Id.* at 36.) Empty and full can tests were positive, petitioner's infraspinatus was weak. (*Id.*) Dr. Cincere noted that she was "over worked

in PT with increased pain, good motion, [rotator cuff] weak." (*Id.* at 37.) Petitioner received a subacromial bursa injection. (*Id.*)

On May 18, 2017, petitioner again returned to Dr. Cincere for a follow-up. (Ex. 4, pp. 7-10; Ex. 14, pp. 30-35.) At three months post-surgery, petitioner voiced improvement with her therapy. (Ex. 4, pp. 7-8.) She also indicated that she was still taking Vimovo which helped. (*Id.* at 8.) Furthermore, petitioner suggested that the swelling had decreased greatly. (*Id.*) On examination petitioner had weak empty and full can tests. (*Id.* at 9.) Petitioner's infraspinatus was intact, and her bear hug and O'Brien's tests were negative. (*Id.*) Petitioner received another subacromial bursa injection in her left shoulder. (*Id.* at 10.)

On June 27, 2017, petitioner presented to Dr. Cincere for a follow-up. (Ex. 4, pp. 4-6; Ex. 14, pp. 27-30.) Petitioner was attending physical therapy twice a week, and said it was effective. (Ex. 4, p. 4.) She indicated that she was "experiencing numbness and tingling from the shoulder down to the left hand." (*Id.*) On examination Dr. Cincere observed tenderness in the ac joint, acromion, biceps tendon, and clavicle. (*Id.* at 5.) Petitioner's Hawkin's and impingement tests were positive. (*Id.* at 6.) Petitioner's left shoulder passive range of motion was 170-90-90-30-50. (*Id.*) Empty and full can tests were painful, petitioner's infraspinatus was intact, and her bear hug, O'Brien's and Speeds tests were negative. (*Id.*) In his assessment Dr. Cincere noted that "since February surgery she [ha]s improvement continue[s] has pain rated radicular type symptoms of paresthesias down into her hand[.]" (*Id.*) Dr. Cincere ordered a repeat EMG. (*Id.*)

On June 28, 2017, petitioner presented to Dr. Regan for pain in her right-side rib cage radiating to the back for the last month causing shortness of breath. (Ex. 2, p. 2.) Dr. Regan ordered a CTA of her lungs to rule out any pulmonary embolus. (*Id.*)

On July 19, 2017, petitioner underwent another EMG. (Ex. 4, pp. 13-14.) On examination, petitioner had limited range of motion in her left shoulder and left neck. (Ex. 4, p. 13.) There was no evidence of cervical radiculopathy, brachial plexopathy, suprascapular neuropathy, left median neuropathy, left ulnar neuropathy, or left radial neuropathy. (*Id.*) The report further indicated that "[petitioner's] previously seen left suprascapular neuropathy based on studies of 02/01/2017 has physiologically resolved following surgery" and "full clinical correlation is suggested." (*Id.*) The same day, petitioner underwent a cervical spine MRI which showed minimal C3-C4 canal and bilateral foraminal stenosis, mild right C4-C5 canal and foraminal stenosis, and mild right and minimal left C5-C6 canal and foraminal stenosis. (Ex. 4, pp. 19-20.) Furthermore, disc desiccation was noted at levels C2-C3, C6-C7, and C7-T1 and disc osteophyte complex were noted at C3-C4, C4-C5, and C5-C6. (*Id.*)

On July 27, 2017, petitioner returned to Dr. Cincere to review her MRI and EMG studies, complaining of left shoulder and neck pain. (Ex. 4, pp. 1-3.) Petitioner rated her pain as 7/10, aggravated by range of motion, associated with weakness, numbness,

tingling, and popping/clicking that "radiates to: down the arm." (*Id.* at 1.) On examination, petitioner experienced tenderness in the cervical region though her left shoulder range of motion was normal. (*Id.* at 2.) Dr. Cincere noted that her c-spine MRI showed "mild degenerative changes foraminal disease C3 through C6 bilaterally." (*Id.* at 3.) In his assessment, Dr. Cincere observed that petitioner continued to complain of neck and trapezial pain, meanwhile "radicular type symptoms improved[,] paresthesias in her left hand[,] complains of swelling around her neck despite shoulder arthroscopy debridement subscapular nerve release." (*Id.* at 3.) Dr. Cincere noted that petitioner's EMG demonstrated "no injuries and resolution of left subscapular neuropathy," and he was referring petitioner to Dr. Keueter for cervical radiculopathy. (*Id.*) Dr. Cincere indicated that "the initial process of how this all started[,] does not seem to make a lot of sense[,] there is no further structural injury of her shoulder that I feel like I can help her with[,] she may need to be referred to a rheumatologist or pain management." (*Id.*)

On September 19, 2017, petitioner presented to Dr. Regan complaining of chronic left shoulder pain and requesting a referral back to physical therapy. (Ex. 2, p. 4.) On examination petitioner had decreased range of motion and tenderness in the left shoulder. (*Id.* at 5.)

On November 8, 2017, petitioner underwent an unrelated sleep apnea consultation. (Ex. 9, pp. 1-3.) Petitioner returned on November 16, 2017, after undergoing a sleepy study, showing accentuated obstructive sleep apnea. (*Id.* at 5-7.)

Petitioner continued physical therapy for her left shoulder and neck pain through approximately February 22, 2018.[9] (Ex. 15.)

b. As reflected in petitioner's affidavits

Petitioner filed her first affidavit on January 11, 2018. (Ex. 8.) Petitioner states that she received a flu shot on November 2, 2016, and sustained shoulder injuries caused by the administration of the vaccine. (Ex. 8, p. 1.)

On March 20, 2018, petitioner filed a supplemental affidavit. (Ex. 12.) Petitioner avers that she felt pain when the pharmacist stuck the needle in her arm. (*Id.* at 1.) "Within 30 minutes" petitioner states that "the pain was so bad and [her] arm was swelling and [she] could not even raise [her] arm." (*Id.*) Having received flu shots in the past, petitioner states that she hoped her arm would get better with ice packs. (*Id.*) Thereafter petitioner called the pharmacy "and explained how [her] arm was swelling and in excruciating pain," such that she could not raise her arm. (*Id.*) Petitioner was advised to fill out a VAERS report. (*Id.*)

On November 11, 2016, petitioner presented to Dr. Teresa Regan, and petitioner recalls that Dr. Regan indicated that "someone had screwed up [her] arm." (Ex. 12, p.

[9] Petitioner's Alliance Physical Therapy billing records, filed as Exhibit 15, indicate that petitioner attended physical therapy through February 22, 2018, although petitioner's updated Alliance Physical Therapy records only provide Daily Notes through December 27, 2018. (*See* Exs. 15, 17.)

1.) Petitioner avers that Dr. Regan wanted to "rule out if it [] caused MRSA so she sent [petitioner] to Erlanger hospital for a CT scan." (*Id.*) Dr. Regan referred petitioner to an orthopedic physician, Dr. Brandon Cincere. (*Id.*)

On November 18, 2016, petitioner presented to Dr. Cincere. (Ex. 12, p. 2.) She states that she was in "excruciating pain" and cried when Dr. Cincere tried to raise her arm. (*Id.*) Dr. Cincere ordered x rays and an MRI. (*Id.*) Petitioner avers that she was "having bad pain in [her] left shoulder arm, hand, and fingers and had pain in [her] neck." (*Id.*) Petitioner was experiencing "tingling all the way down her arm, and into [her] fingers, so they moved [her] MRI with contrast up to November 30, 2016." (*Id.*) Petitioner presented to Dr. Cincere again on December 20, 2016, for a follow-up visit after her MRI, at which point petitioner avers that she "still couldn't use [her] left arm." (*Id.*)

On January 3, 2017, petitioner presented to a walk-in clinic and she avers that her arm was swelling "so badly that [she] couldn't move [her] neck." (Ex. 12, p. 2.) Dr. Rae prescribed petitioner Robaxin. (*Id.*) The next day petitioner called Dr. Regan who advised her to come in immediately and "said the flu shot has set up bursitis." (*Id.*) Petitioner "couldn't move [her] arm and [her] neck was stiff." (*Id.*)

On February 1, 2017, petitioner presented to Chattanooga Imaging for an EMG and Dr. Kadrie "said it had caused nerve damage in [her] left shoulder." (Ex. 12, p. 2.) On February 7, 2017, petitioner presented to Dr. Cincere, who scheduled surgery "due to the nerve damage, muscle weakness, and pain" in her left shoulder. (*Id.*) At the time petitioner needed assistance with dressing, household chores, and driving. (*Id.*) Petitioner underwent left shoulder surgery on February 22, 2017. (*Id.*) After surgery, petitioner was told by Dr. Cincere "not to lift more than a pencil" and to wear a brace for six weeks. (*Id.*) Petitioner attended physical therapy 2x a week, and later returned to work as a nurse two days a week because she still experienced "a lot of shoulder and neck pain[.]" (*Id.*)

IV. Summary of Expert Opinions

a. Petitioner's expert Naveed Natanzi, D.O.

Dr. Natanzi currently serves as the Medical Director for Tova Surgical Center and as the Staff Physician for the VA Long Beach Healthcare System. (Ex. 24, p. 1.) He is also a founder at Regenerative Sports and Spine Institute. (*Id.*) Dr. Natanzi received his medical degree from Western University of Health Sciences in 2012. (*Id.* at 2.) Dr. Natanzi completed his residency at the University of California Irvine Physical Medicine and Rehabilitation department. (*Id.* at 1.) He was also an attending physician in Interventional Regenerative Sports and Spine medicine at the Bodor Clinic. (*Id.*) Dr. Natanzi was trained by Dr. Marko Bodor, the first to describe shoulder injuries related to vaccine administration in medical literature. (Ex. 18, p. 1.) Dr. Natanzi is board certified by the American Academy of Physical Medicine and Rehabilitation as well as the

American Board of Pain Management. (Ex. 24, p. 1.) On average, he diagnoses and treats 40 to 50 shoulder and 200 to 300 cervical and lumbar pathologies per month. (Ex. 19, p. 1.)

Dr. Natanzi opines that there is a clear temporal relationship between vaccination and onset of petitioner's symptoms; and her clinical scenario is well in line with the generally accepted timeframe in SIRVA cases. (Ex. 18, p. 7.) He observes that petitioner first presented to Dr. Regan on November 11, 2016, nine days post-vaccination with limited range of motion which began shortly after vaccination. (*Id.*) Dr. Regan noted the injection site to be "to[o] far superior," which Dr. Natanzi explains is known to increase the likelihood of vaccine overpenetration.[10] (*Id.*) On December 20, 2016, petitioner was diagnosed with shoulder impingement, rotator cuff tendinosis, and subacromial bursitis by Dr. Cincere. (*Id.*) Petitioner's bursitis diagnosis was further confirmed by Dr. Cincere intraoperatively on February 22, 2017, where he identified thickened bursal tissue, Dr. Natanzi explains. (*Id.*) Dr. Natanzi highlights three key points in petitioner's case: her prior influenza vaccination on October 21, 2015, the onset of her symptoms immediately after vaccination, and petitioner's prolonged inflammatory-like clinical reaction—which all suggest a causal relationship between petitioner's November 2, 2016 vaccination and her symptoms. (*Id.*)

Dr. Natanzi observes that Dr. Cincere offered a possible diagnosis of cervical radiculopathy on June 27, 2017. (Ex. 18, p. 8.) However, Dr. Natanzi stresses that an MRI of petitioner's cervical spine (7/19/2017) and two NCS/EMGs (2/1/2017; 7/19/2017) revealed no signs of radiculopathy or cervical spine pathology that would explain petitioner's symptoms. (Ex. 18, p. 8.) Given petitioner's lack of any history of cervical symptoms, her benign diagnostic testing, and the acute development of her symptoms after vaccination, he opines that contribution of symptoms from the cervical spine (i.e. cervical radiculopathy or facet syndrome) are "exceedingly unlikely." (*Id.*)

Dr. Natanzi acknowledged that on November 11, 2016, Dr. Regan noted numbness and tingling in the left hand, beginning along with the shoulder symptoms after vaccination. (Ex. 18, p. 8.) Dr. Natanzi explains that "[r]adiating pains associated with numbness and tingling are common findings in cases of SIRVA." (*Id.*) In fact, he notes that Atanasoff et al. recorded altered sensation in the ipsilateral limb after SIRVA in four patients out of a cohort of thirteen. (*Id.* (*see* S. Atansoff et al., *Shoulder injury related to vaccine administration (SIRVA),* 28 VACCINE 8049 (2010) (Ex. 18.5).) Likewise, Dr. Natanzi points to Okur et al., who described a cool, numb, and heavy sensation with radiating pains along the affected limb in SIRVA patients immediately

[10] Dr. Nantanzi further observes that overpenetration is increasingly likely in petitioner's case given the proximal injection site, as witnessed by Dr. Regan, the standing position of the injector while petitioner was seated, and her resting (non-abducted left arm position). (Ex. 18, p. 9 (citing Ian cook, *An evidence based protocol for the prevention of upper arm injury related to vaccine administration (UAIRVA),* 7.8 Human Vaccines 845 (2011) (Ex. 18.4); Atanasoff et al., *supra,* at Ex. 18.5; Gail Cross et al., *Don't aim too high: Avoiding shoulder injury related to vaccine administration,* 45.5 Australian Family Phys. 303 (2016) (Ex. 18.11).))

after vaccination. (Ex. 18, p. 8 (*see* Gokcan Okur et al., *Magnetic resonance imaging of abnormal shoulder pain following influenza vaccination,* 43 SKELETAL. RADIOL. 1325 (2014) (Ex. 18.8).) Without any objective findings to suggest otherwise, either in petitioner's MRI or EMG/NCS, Dr. Natanzi opines that petitioner's hand numbness and tingling were "related directly to SIRVA." (Ex. 18, p. 8.)

Dr. Natanzi observed that petitioner's NCS/EMG on February 1, 2017, revealed signs of a left suprascapular neuropathy. (Ex. 18, p. 8.) According to Dr. Natanzi, suprascapular neuropathy is a relatively rare diagnosis that often presents in athletes or heavy laborers. (Ex. 18, p. 8.) The mechanism of injury is typically related to a traction type injury related to trauma, or as a result of anatomical compression. (*Id.* (citing Anthony Romeo et al., *Suprascapular Neuropathy,* 7 J. AM. ACAD. ORTHOP. SURG. 358 (1999) (Ex. 18.14)).) Dr. Natanzi finds that petitioner had no history of such injuries in the clinical history, or evidence of an anatomical compression in the MRI or operative report by Dr. Cincere. (Ex. 18, p. 8.) Despite a surgical release by Dr. Cincere on February 22, 2017, and resolution of the previously identified suprascapular neuropathy on a follow-up EMG (7/19/2017), Dr. Natanzi notes that there were no signs of clinical improvement in petitioner's symptoms. (*Id.*) He opines that the findings of suprascapular neuropathy were subclinical and unrelated to petitioner's shoulder symptoms—and thus does not preclude a SIRVA diagnosis. (Ex. 18, p. 8.)

b. Respondent's Expert, Geoffrey Abrams, M.D.

Dr. Abrams currently serves as Assistant Professor of Orthopedic Surgery at the Stanford University School of Medicine. (Ex. A, p. 1.) He also holds the appointment of Staff Physician at the Veterans Administration Palo Alto Health Care Division. (*Id.*) Dr. Abrams is the Director of Sports Medicine for Stanford University Varsity Athletics as well as Director of the Lacob Family Sports Medicine Center at Stanford University. (*Id.*) He also serves as Team Physician for numerous professional and collegiate sports teams in the San Francisco Bay Area. (*Id.*) Dr. Abrams received his medical degree from the University of California San Diego. (Ex. C, p. 1.) He competed a surgical internship at Stanford University Hospital and Clinics from 2007 to 2008; and completed his residency in 2012 at the same hospital in the Department of Orthopedic Surgery. (*Id.*) Dr. Abrams also has a subspecialty certificate in Orthopedic Sports Medicine. (*Id.* at 2.) He has a surgical practice focused on orthopedic conditions of the shoulder and authored or co-authored over sixty peer-reviewed medical articles on various orthopedic topics. (Ex. A, p. 1; Ex. C, pp. 2-8.)

Dr. Abrams observes that petitioner experienced pain not only in the shoulder, but also numbness, pain and tingling into the left hand as well as pain in the neck. (Ex. A, p. 3 (citing Ex. 2, p. 18; Ex. 10, p. 3).) While some suspected cases of SIRVA can have pain in the shoulder area that may radiate to the upper arm, Dr. Abrams explains that numbness and tingling are classic findings of a neurogenic pathology. (*Id.* (citing P. Marchettini et al., *Painful Peripheral Neuropathies,* 4 CURRENT NEUROPHARM. 175 (2006) (Ex. A.10)).) In contrast, Atanasoff et al. reported that "sensory symptoms such as

tingling and numbness in the affected extremity were uncommon" among SIRVA cases. (Ex. A, p. 3-4 (quoting Atanasoff et al., *supra,* at Ex. A.1).)

Dr. Abrams acknowledges that suprascapular neuropathy is not likely to cause numbness and tingling to the hand. (Ex. A, p. 4.) However, he opines that there is another reason to suspect that petitioner's pain, numbness, and tingling may be related to *another* neurogenic cause – her cervical spine. (*Id.*) Given her neck and shoulder pain, as well as numbness and tingling into the hand, Dr. Abrams stresses that a number of petitioner's providers suspected and evaluated her for cervical spine pathology. (*Id.*) Dr. Abrams notes that petitioner's MRI of the cervical spine demonstrated C4/5 bilateral narrowing and stenosis as well as C5/6 left foraminal and canal stenosis from paracentral disc osteophyte complex. (Ex. A, p. 4 (citing Ex 4, p. 19; Ex 14, p. 36.).) In radicular symptoms originating from the cervical spine, Dr. Abrams explains that the exiting nerve root is often involved, which is the lower number of the disc complex at any particular level.[11] (Ex. A, p. 4.) He observes that petitioner's MRI from July 19, 2017, indicated left sided pathology at both of these levels. (*Id.*) Dr. Abram further explains that "the C5 nerve root gives a sensation and/or pain to the shoulder and lateral upper extremity while the C6 nerve root gives sensation and/or pain pattern to the lateral forearm and digits (hand)." (Ex. A, p. 4.) These pain patterns are consistent with the petitioner's stated location of her symptoms, Dr. Abrams opines. (*Id.*)

Furthermore, Dr. Abrams notes evidence of spondylosis, or degenerative changes, in petitioner's cervical MRI taken on July 19, 2017. (Ex. A, p. 4.) According to Dr. Abrams, this is evidenced in the MRI report as "disc desiccation" and reported at nearly all levels. He explains that cervical spondylosis is a well-documented cause of neck pain. (*Id.* (citing Ginger Evans, *Identifying and Treating the Causes of Neck Pain,* 98 MED. CLIN. N. AM. 645 (2014) (Ex. A.6)).) Furthermore, he suggests that cervical spondylosis can also lead to referred pain to the upper extremities – including the shoulder area. (Ex. A, p. 4 (citing Evans, *supra,* at Ex. A.6).) Dr. Abrams explains that the mechanism of this "stems from nociceptive afferents from facet joints that converge in the spinal cord with nociceptive afferents from other distal sites." (Ex. A, p. 4 (citing Nikolai Bogduk, *The Anatomy and Pathophysiology of Neck Pain,* 22 PHYS. MED. REHABIL. CLIN. N. AM. 367 (2011) (Ex. A.3); Grant Cooper et al., *Cervical Zygaphophysial Joint Pain Maps,* 8(4) PAIN MEDICINE 344 (2007) (Ex. A.5); Nalini Sehgal et al., *Systematic Review of Diagnostic Utility of Facet (Zygapophysial) Joint Injections in chronic Spinal Pain: An Update,* 10 PAIN PHYS. 213 (2007) (Ex. A.13)).) Moreover, Dr. Abrams notes that Cooper et al. reported over half of their patients with cervical spondylosis at C5/6 suffered shoulder/lateral arm/deltoid pain in addition to neck pain. (Ex. 8, pp. 4-5 (citing Cooper et al., *supra,* at Ex. A.13).)

Regarding petitioner's diagnosis of left suprascapular neuropathy, Dr. Abrams opines that suprascapular neuropathy is a source of shoulder pain, one where patients

[11] For instance, Dr. Abram explains that at the C4/5 level the C5 nerve root would most often be affected while at the C5/6 level the C6 nerve root is involved. (Ex. A, p. 4.)

often present with pain to the superior and posterolateral aspect of the shoulder, often radiating to the neck or lateral arm. (Ex. A, p. 5 (citing Lazaros Kostretzis et al., *Suprascapular Nerve Pathology: A Review of the Literature,* 11 Open Ortho. J. 140 (2017) (Ex. A.9)).) Dr. Abrams disagrees with Dr. Natanzi's assessment that suprascapular neuropathy is an uncommon diagnosis. Rather, Dr. Abrams stresses that suprascapular neuropathy is actually a well-documented source of shoulder pain. (Ex. A, p. 5 (citing Neil Ghodadra et al., *Arthroscopic Decompression of the Suprascapular Nerve at the Spinoglenoid Notch and Suprascapular Notch Through the Subacromial Space,* 25(4) J. ARTHROSCOPIC AND RELATED SURG. 439 (2009) (Ex. A.8); Amit Momaya, et al., *Clinical outcomes of suprascapular nerve decompression: a systematic review,* 27 J. SHOULDER ELBOW SURG. 172 (2018) (Ex. A.11); Dana Piasecki, *Suprascapular Neuropathy,* 17(11) J. AM. ACAD. ORTHOP. SURG. 665 (2009) (Ex. A.12)).) Rarely is there a history of acute trauma in those with a diagnosis of suprascapular neuropathy, Dr. Abrams stresses. (Ex. A, p. 5 (citing Ghodara et al., *supra,* at Ex. A.8; Momaya et al., *supra,* at Ex. A.11).) Furthermore, Dr. Abrams suggests that it is expected that some patients with suprascapular neuropathy will have normal MRIs. (Ex. A, p. 5.) There are three typical sources of suprascapular nerve compression: 1) space occupying lesion such as a paralabral cyst, 2) traction injury, and 3) hypertrophic suprascapular ligament and/or narrowed suprascapular notch. (*Id.* (citing Piasecki, *supra,* at Ex. A.12).) In the latter two scenarios, Dr. Abrams stresses that MRIs will not have any direct finding of suprascapular nerve pathology in the early stages of the disease. (Ex. A, p. 5.) Instead, the EMG results are used to diagnose the disorder.

Therefore, in petitioner's case, Dr. Abrams opines that the results of petitioner's first EMG on February 1, 2017, as well as the MRI of the shoulder on November 30, 2016, suggest that petitioner's suprascapular neuropathy was present only for a relatively short time. (Ex. A, p. 5.) In fact, Dr. Abrams opines that "it would be reasonable to conclude that this nerve pathology may have arisen around the time of the injection." (*Id.*) Dr. Abrams draws this conclusion based on the abnormal muscle response of the supraspinatus and infraspinatus on the EMG evaluation[12] combined with the finding of no significant loss of muscle bulk/mass and/or fatty infiltration seen within these muscles on the MRI. (*Id.*) In the setting of chronic muscle denervation (in this instance, the supraspinatus and infraspinatus muscles of the rotator cuff), Dr. Abrams opines that "one would expect to see loss of muscles mass and fatty infiltration/atrophy on the MRI." (Ex. A, p. 5.) However, he notes that this is not noted in the MRI report, indicating that the motor endplates and synaptic connections between the nerve and muscle had not fully degenerated. (*Id.* (citing Meredith Wilson & Michael Deschenes, *The neuromuscular junction: Anatomical features and adaptations to various forms of increased, or decreased neuromuscular activity,* 115 INTERN. J.

[12] Furthermore, Dr. Abrams opines, that a patient may experience clinical symptoms of shoulder pain despite having a normal EMG/NCS evaluation for suprascapular neuropathy. (Ex. A, p. 5.) Citing Freehill et al., Dr. Abrams notes that while electromyography and nerve conduction velocity studies are the "gold standard for confirmation of the diagnosis of suprascapular neuropathy…nerve pain may occur even in the setting of a negative electromyography." (*Id.* (citing Michael Freehill, *Suprascapular Neuropathy: Diagnosis and Management,* 40(1) PHYS. AND SPORTSMEDICINE 72 (2012) (Ex. A.7)).) This would provide a plausible explanation for petitioner's continued pain following her suprascapular nerve decompression performed by Dr. Cincere, Dr. Abrams opines. (Ex. A, p. 5.)

NEUROSCIENCE 803 (2005) (Ex. A.14)).) Therefore, he concludes that "the suprascapular nerve pathology had been present over a time period of months, not years, and certainly could have begun to manifest itself around the time of the 2016 vaccination." (Ex. A, p. 5.)

Dr. Abrams further disagrees with Dr. Nantanzi's theory of over-penetration of the needle into petitioner's shoulder, leading to an inflammatory reaction in the subacromial space. (Ex. A, p. 6.) First, Dr. Abrams stresses that petitioner did not experience pain relief with the pre-operative subacromial bursa injections or the shoulder arthroscopy, both meant to address the location of the alleged SIRVA insult. (*Id.*) This offers an alternative explanation for petitioner's shoulder pain: either cervical etiology and/or residual suprascapular nerve disfunction even after the surgical decompression. (*Id.*) Second, Dr. Abrams suggests that the medical literature cited by Dr. Nantanzi is not persuasive. (*Id.*) In both cases of needle over-penetration studied by Bodor et al., the patients experienced complete pain relief with subacromial bursa-directed corticosteroid injections. (*Id.* (citing Bodor et al., *supra,* at Ex. A.2).) This was not the case with petitioner. (Ex. A, p. 6.) Trollmo et al. examined systemic inflammatory effect of intra-articular injection to the knee and wrist in experimental and control subjects. (*Id.* (citing Trollmo et al., *supra,* at Ex. 18.1).) However, Dr. Abrams stresses that there is no evidence that petitioner received an intra-articular injection; and according to Dr. Nantazi, petitioner received, possibly, a sub-deltoid or subacromial vaccination. (Ex. A, p. 6.) Even still, Dr. Abrams notes that the intra-articular space of the glenohumeral joint differs substantially in anatomy and composition from the subacromial space. (*Id.*) Finally, Dr. Abrams observes that Barnes et al., Uchida et al., and Okur et al. report that patients in their case series had MRI findings of either bone bruising, subacromial effusion, and/or fluid signal in the deep muscular layers. (*Id.*) According to Dr. Abrams, there is no evidence of any of these findings in the radiology report from petitioner's November 30, 2016 MRI.[13] (*Id.*)

c. Dr. Natanzi's First Supplemental Expert Report

As is common in SIRVA cases, Dr. Natanzi notes that secondary compensational issues may develop as a result of "favoring the shoulder." (Ex. 19, p. 2.) In petitioner's case, Dr. Natanzi opines that her shoulder pain and reduced glenohumeral joint range of motion have resulted in overuse, malpositioning, and imbalance of the scapulothoracic joint. (*Id.*) As a result, muscles of this joint that have attachments to the cervical spine (namely the levator scapulae and upper trapezius) exert altered and atypical forces/strain on the cervical spine and cause cervical mediated signs, symptoms, and pathology. (*Id.*) Dr. Natanzi opines that this phenomenon is particularly

[13] In petitioner's shoulder MRI, Dr. Cincere reported evidence of "left shoulder bursal signal changes RTC signal changes." (Ex. A, p. 6 (citing Ex. 4, p. 29).) However, Dr. Abrams highlights the operative report, which states that the bursal side of the rotator cuff was "completely intact." (Ex. A, p. 6 (citing (Ex. 4, p. 23).) According to Dr. Abrams, many of the SIRVA cases in the literature that claim needle over-penetration result in bursal-sided rotator cuff pathology. (Ex. A, p. 6 (citing Bodor et al., *supra,* at Ex. 18.2; Atanasoff et al., *supra,* at Ex. 18.1).) These findings were not seen in petitioner's MRI or noted by Dr. Cincere during surgery.

likely in petitioner's case given the delayed onset of cervical symptoms, beginning approximately 2 months post-vaccination on January 3. (*Id.* (citing Ex. 10, p. 4).) Dr. Natanzi opines that petitioner "likely experienced myofascial and facet sprain/strain symptoms as a result of favoring her shoulder." (Ex. 19, p. 2.) In support, Dr. Natanzi cites a case study by Escobar et al., who described a trigger point in a part of the rotator cuff (teres minor) with radiating symptoms into the ring and little fingers. (Ex. 19, p. 2 (citing Pedro Luis Escobar & Julian Ballesteros, *Teres Minor: Source of Symptoms Resembling Ulnar Neuropathy or C8 Radiculopathy,* 67.3 Am. J. Physical Med. & Rehab. 120 (1988) (Ex. 19.3)).) Although the teres minor was not the specific rotator cuff muscle affected in petitioner's case, Dr. Natanzi opines that "there are likely other rotator cuff 'trigger points' that may account for additional anomalous neuropathic pain referral patterns as experienced by [petitioner]." (Ex. 19, p. 2.) Thus, he opines that the paresthesia-like sensations petitioner felt immediately post-vaccination in the ipsilateral limb were "related to a rotator cuff referral pattern" and therefore "unrelated to the cervical spine." (*Id.*)

Lastly, based on his experience and discussions with Dr. Bodor, Dr. Natanzi explains that he has seen cases similar to petitioner's, and attributes the refractory symptoms to the vaccine remaining embedded in the rotator cuff tendons. (Ex. 19, p. 2-3.) Dr. Natanzi explains that the vaccine can become lodged within the tendon itself—and would be invisible to the naked eye or an arthroscopy camera and therefore undetectable and untreatable with arthroscopic surgery.[14] (*Id.*) Ultimately, he explains that "shoulder pain associated with compensatory neck pain" can exist and does not preclude a SIRVA diagnosis. (*Id.*)

d. Dr. Abrams' Supplemental Expert Report

In his supplemental expert, Dr. Abrams stresses that there are irrefutable facts that argue against a SIRVA related diagnosis. (Ex. C, p. 1.) First, Dr. Abrams observes once again that petitioner's MRI taken approximately four weeks post-vaccination did not show any of the signs of SIRVA—bursitis, bursal sided rotator cuff pathology, bone edema, etc. (*Id.*) Dr. Abrams notes that Dr. Natanzi relies on Dr. Cincere's report (Ex. 14, p. 2), concluding that there are objective signs of bursitis and tendinopathy on petitioner's MRI. (*Id.* (citing Ex. 19, p. 1).) Closer examination reveals that Dr. Cincere disagreed with the radiologist's report on the axial images, a series of images that are rarely utilized for viewing bursitis, according to Dr. Abrams. (Ex. C, p. 1 (citing Ex. 14, p. 2).) Moreover, Dr. Abrams stresses that Dr. Cincere used the term "bursal changes" but nowhere in his note from this visit does he state that he sees inflammation or fluid in the bursa. (Ex. C, p. 1.)

[14] Dr. Natanzi further describes a procedure known as the Tenex procedure, an ultrasound guided percutaneous tenotomy, in which the vaccine is "cleaned out" of the tendon. (Ex. 19, p. 3.) Dr. Natanzi observes that Dr. Bodor's preliminary data has shown a near-complete resolution of shoulder pain in similar cases after this procedure—lending further supporting to this theory. (*Id.*)

Second, Dr. Abrams disputes the onset of petitioner's neck pain and cervical-related symptoms. (Ex. C, p. 1.) Dr. Abrams points to records indicating that petitioner's "numbness, pain and tingling to the left hand" began five days following the injection, not two months later (as Dr. Natanzi proposes). (*Id.* (citing Ex. 2, p. 18).) This would make Dr. Natanzi's mechanism for a compensational pattern of shoulder pain less likely, according to Dr. Abrams. (Ex. C, p. 1.) Furthermore, Dr. Abrams stresses that there are several other possible sources for petitioner's neck pain that are objectively documented in her medical history, including C5/6 left foraminal and canal stenosis from paracentral disc osteophyte complex, spondylosis or "disc desiccation," and negative EMG (with suprascapular nerve findings). (Ex. C, p. 1 (citing Ex. 4, pp. 19, 24-25; Ex. 14, pp. 19, 36).)

Third, Dr. Abrams maintains that petitioner did not receive any improvement in symptoms with the administration of a corticosteroid injection. (Ex. C, p. 3.) Dr. Abrams disagrees with Dr. Natanzi's theory suggesting the vaccine could be lodged in the tendon itself; and Dr. Abrams stresses the lack of objective evidence supporting this theory. (*Id.*) Nonetheless, Dr. Abrams stresses that if Dr. Natanzi's theory is possible, it would likely incite some inflammatory process within the tendon itself—which again was not seen on the shoulder MRI four weeks post-vaccination. (*Id.*)

Lastly, Dr. Abrams emphasizes the record from petitioner's visit with Dr. Regan nine days post-vaccination. (Ex. C, p. 3 (citing Ex. 2, p. 18).) Dr. Regan offered statements about the location of the injection in the history of present illness section; however, the section memorializing the physical exam did not include any evidence that the examiner was able to see the location of the injection. (Ex. C, p. 3 (citing Ex. 2, p. 18).) Furthermore, Dr. Abrams suggests that the outside of a skin reaction to the injection (of which there was no mention) and the location of needle penetration to the skin would be difficult to visualize nine days following vaccination. (Ex. C, p. 3.)

e. Dr. Natanzi's Second Supplemental Expert Report

In his second supplemental expert report, Dr. Natanzi suggests that "Dr. Abrams agrees that TOS [thoracic outlet syndrome] is not the source of [petitioner's] ongoing shoulder pain given his comments on page 3 of his supplemental expert report (Exhibit C)."[15] (Ex. 20, p. 1.) He further finds that Dr. Abrams "[e]ssentially agrees that given the ongoing pain – despite surgical decompression of the suprascapular nerve in conjunction with the subsequent negative (normal) EMG – the suprascapular nerve cannot be a source of ongoing pain." (*Id.*)

Dr. Natanzi agrees that a sensory radiculopathy could be the source of radicular symptoms in light of a negative EMG; and that cervical radiculopathy can cause shoulder pain and upper limb paresthesia. (Ex. 20, p. 1.) However, Dr. Natanzi maintains that cervical radiculopathy was not the likely cause of petitioner's pain, for

[15] Dr. Abrams does not appear to discuss thoracic outlet syndrome on page 3 of Exhibit C or otherwise. (*See* Ex. C.)

three reasons. (*Id.* at 2.) First, he stresses that petitioner never had any history of neck pain or upper limb symptoms prior to the date of vaccination. (*Id.*) For symptoms of a neck disorder (cervical radiculopathy) to have surfaced spontaneously after five decades of life, and coincidentally days after a shoulder injection (that can independently explain petitioner's symptoms), is very unlikely—Dr. Natanzi explains. (*Id.*) Second, Dr. Natanzi suggests that multiple physical exams demonstrate signs of impingement and a restricted shoulder range of motion, which are indicative of a shoulder pathology, and would not be expected in the context of a cervical issue like radiculopathy. (*Id.*) Lastly, he emphasizes the fact that an orthopaedic surgeon performed surgery on the shoulder, and "[c]learly he would not have done so if he even suspected the pain was stemming from her neck." (Ex. 20, p. 2.)

Dr. Natanzi again stresses that trigger points in the rotator cuff can cause symptoms that extend into the hand. (Ex. 20, p. 2 (citing Escobar et al., *supra,* at Ex. 19.3; Okur et al., *supra,* at Ex. 18.8; Atanasoff et al., *supra,* at Ex. 18.5).) To demonstrate, Dr. Natanzi cites a study of 94 patients with various shoulder pathologies where the authors mapped out pain symptom patterns from the level of the shoulder all the way to the hand. (Ex. 20, p. 2 (citing Levent Bayam et al., *Pain Mapping for Common Shoulder Disorders,* 40(7) AM. J. ORTHOP. 353 (2011) (Ex. 20.3)).) Similar to petitioner's case, Dr. Natanzi identifies 28 patients in that study who were diagnosed with impingement syndrome, of which 9 of 28 (32%) had a sense of dull aching pain below the elbow (forearm and hand) and 7 of 28 (25%) had pins and needles sensations in the hand. (Ex. 20, p. 2 (citing Bayam et al., *supra,* at Ex. 20.3).) Although symptoms radiating to the hand is more commonly seen in the setting of cervical radiculopathy, Dr. Natanzi explains that these symptoms can also be seen in the setting of rotator cuff-mediated pain. (Ex. 20, p. 2.)

Lastly, Dr. Natanzi indicates that he reviewed the MRI images and opines that "there are clear signs of subacromial fluid accumulation (bursitis) [and] these findings complement Dr. Cincere's 12/20/16 clinical findings of impingement." (Ex. 20, p. 3 (citing Ex. 14, p. 2).) In response to Dr. Abrams, Dr. Natanzi stresses that "this is one piece of data that is clearly objective and not left to interpretation." (Ex. 20, p. 3.) This finding, Dr. Natanzi adds, complements Dr. Cincere's intraoperative findings of 2/22/17 in which Dr. Cincere identified thickened bursal tissue, which is expected in bursitis. (*Id.*) Reviewing Dr. Zand's report (discussed below), Dr. Natanzi notes that Dr. Zand traced the distance from the skin to the subacromial space (the path the needle would travel) and measured it to be 18 to 20 millimeters. (Ex. 20, p. 3 (citing Ex. 21).) According to Dr. Natanzi, a typical vaccination needle measures 25.4 mm. (Ex. 20, p. 3.) He explains that with an improper technique, it is clear that the vaccine needle is long enough to have caused penetration into the subacromial bursa and underlying rotator cuff, causing petitioner's bursitis and rotator cuff tendinopathy. (*Id.*)

f. Petitioner's expert, Tinoosh Zand, M.D.

Dr. Zand currently serves as a Senior Partner radiologist and Director of the quality control committee at Focus Medical Imaging. (Ex. 22, p. 2.) He is a board-certified diagnostic radiologist in private practice since 2020. (Ex. 21, p. 1.) Dr. Zand received his medical degree from Rosalind Franklin University at the Chicago Medical School in 2003. (Ex. 22, p. 1.) He did his diagnostic radiology residency at Harvard Medical School / Mount Auburn Hospital and his subspeciality fellowship training in musculoskeletal imaging at the University of Southern California. (Ex. 21, p. 1.) Dr. Zand interprets approximately 3000-4000 MRI examinations a year; and the majority of the examinations are of the shoulder, knee, cervical spine, and lumbar spine. (*Id.*)

Dr. Zand reviewed petitioner's MRI arthrogram of the left shoulder taken on November 30, 2016, as well as the MRI results by John Nelson, M.D. (Ex. 21, p. 1.) Dr. Zand explained that the MRI arthrogram of the left shoulder included the following sequences: axial T1 and T2 DE3D WE, coronal oblique T1, T1FS and T2FS, sagittal oblique T2. (*Id.*) Dr. Zand observed the following: 1) mild acromioclavicular joint arthrosis with capsular hypertrophy and edema; 2) mild subacromial / subdeltoid bursitis; 3) moderate thickening and intermediate signal in the supraspinatus tendon representing tendinosis; 4) thickening and intermediate signal in the intra-articular portion of the long head of the biceps tendon representing tendinosis; 5) thinning of the posterior labrum which may be secondary to a chronic labral tear; 6) adequate joint distention without extravasation of contrast into the subacromial / subdeltoid bursa. (*Id.*) Lastly, Dr. Zand measured the deltoid fat pad and muscle thickness at the level of the greater tuberosity of the humeral head from the skin to the lateral aspect of the subacromial / subdeltoid and found the distance to be 18-20 mm on the coronal oblique T2 FS sequence depending on the angle of measurement. (*Id.* at 2.)

V. Party Positions

a. Petitioner's contentions

Petitioner stresses that she suffered a left-sided shoulder injury meeting all four criteria demonstrating a SIRVA Table injury. (ECF No. 49, p. 9.) Alternatively, petitioner asserts that reliable medical evidence supports a non-Table injury was caused-in-fact by her vaccination. (*Id.* at 15.)

In support of her Table claim, petitioner stresses that her symptoms were limited to the left shoulder and that no other condition or abnormality would explain her symptoms. (ECF No. 49, p. 10.) Specifically, petitioner suggests that this is a "classic left SIRVA injury with symptoms limited to the left shoulder, and a subsequent, distinct cervical injury beginning on or around December 31, 2016." (*Id.*) Petitioner "does not dispute that she suffered from cervical symptoms throughout her course of treatment for the SIRVA injury." (*Id.*) Rather, petitioner asserts that symptoms radiating into the hand can be seen in a SIRVA injury and petitioner's complaints of cervical issues developed

in January 2017 when she developed neck pain after waking up with a "crick" in her neck. (*Id.* at 11.) Furthermore, petitioner posits that the language "limited to the shoulder" was not meant to bar a case with a "clear root shoulder injury with associated radiating symptoms[.]" (*Id.* at 12 (citing 42 C.F.R. § 100.3(c)(10)).) Next, petitioner argues that neither cervical radiculopathy nor suprascapular neuropathy were the cause of petitioner's left shoulder pain. (ECF No. 49, p. 12.) In support of petitioner's argument, her expert opines that petitioner's suprascapular neuropathy was subclinical and unrelated to the shoulder symptoms experienced by petitioner post-vaccination and diagnosed by MRI. (*Id.* at 12-13.) Moreover, petitioner's expert explains that her cervical symptoms were not the likely cause of her shoulder pain because petitioner did not have a prior history of neck or upper limb pain, petitioner's EMG results were negative, and petitioner's physical examinations demonstrated signs of impingement and reduced range of motion—which strongly point to shoulder pathology as the source of her pain. (*Id.* at 13-14.)

In support of her causation-in-fact claim, petitioner asserts that she has satisfied all three *Althen* prongs. (ECF No. 49, pp. 15-20.) Under prong one, petitioner requests that this Court take judicial notice that SIRVA has been added to the Vaccine Injury Table for the influenza vaccine, and therefore petitioner has met her burden under prong one requiring preponderant evidence of a medical theory connecting the flu vaccine to SIRVA. (*Id.* at 15.) Alternatively, petitioner relies on the medical literature cited by Dr. Natanzi—describing over 80 cases of immune-mediated inflammatory reactions as a result of vaccination. (*Id.* (citing Ex. 18.1-18.11.)) The proposed mechanism of injury, petitioner alleges, "is the unintentional injection of antigenic material into synovial tissues and / or the subdeltoid bursa causing an immune-mediated inflammatory reaction." (ECF No. 49, p. 15 (quoting Atanasoff et al., *supra,* Ex. 18.5).) Under prong two, petitioner stresses that she had no prior history of injury to her left upper extremity and presented to her primary care physician nine days post-vaccination with redness, swelling, and limited range of motion. (ECF No. 49, p. 16.) Moreover, petitioner's PCP observed that the injection site was "too far superior." (*Id.*) Petitioner was subsequently diagnosed with impingement syndrome, rotator cuff tendonitis, and bursitis by her orthopedist Dr. Cincere. (*Id.*) Taken together, petitioner asserts that she has demonstrated a logical sequence of cause and effect showing that the vaccination was the cause of her injuries. (*Id.*) Finally, under the third prong, petitioner stresses that she presented to her PCP nine days post-vaccination reporting shoulder pain and limited range of motion since receiving her flu shot. (*Id.* at 19.) Petitioner suggests that the Vaccine Table and SIRVA QAI establish a 48-hour medically acceptable timeframe for the onset of symptoms. (*Id.*) Furthermore, petitioner cites her affidavit, where she described pain when the vaccine was administered and swelling within 30 minutes after her vaccination. (*Id.*)

In response to respondent's contentions, petitioner stresses that she has preponderantly demonstrated a logical sequence of cause and effect showing that the vaccination was the cause of her injuries. (ECF No. 57, pp. 2-3.) Petitioner stresses

that Dr. Cincere's July 27, 2017, report noted that there was no *further* structural damage to the shoulder—because her left shoulder was surgically repaired five months prior to this visit. (*Id.* at 2.) Additionally, petitioner argues that she demonstrated improvement following surgery, albeit inconsistently. (*Id.*) Therefore, petitioner argues that it is speculative to conclude that because petitioner continued to have symptoms following surgery that the shoulder injury was not a continual source of those symptoms. (*Id.*) Finally, petitioner maintains that petitioner was diagnosed with subacromial bursitis and tendonitis. (*Id.* at 3.) While respondent argues that the bursal side of petitioner's rotator cuff was found intact during surgery, petitioner highlights the February 22, 2017, surgical report which indicates "extensive subacromial bursitis." (*Id.*) Petitioner stresses that these diagnoses are "hallmark SIRVA diagnoses." (*Id.*)

b. Respondent's contentions

Respondent argues that petitioner is not entitled to compensation because she has not met the elements for a Table SIRVA nor has she presented preponderant evidence showing that her injury was caused-in-fact by her influenza vaccination. (ECF No. 51, pp. 6, 8.)

Specifically, respondent stresses that petitioner's pain was not limited to her left shoulder, and that other conditions explain her symptoms. (ECF No. 51, pp. 6-7.) Respondent suggests that petitioner likely experienced numbness and tingling in her hand in her first visit with her PCP on November 11, 2016, and later records specifically indicate that petitioner had numbness and tingling in the second, third, and fourth digits of the left hand. (*Id.* at 6-7.) Moreover, respondent argues that the fact that pins-and-needles sensations in the hand have been reported with shoulder impingement is not relevant. (*Id.* at 7 (citing ECF No. 49, p. 11).) Respondent contends that petitioner has failed to satisfy the criteria set forth in the Vaccine Injury Table QAIs that would entitle her to a presumption of vaccine causation. (ECF No. 51, p. 7.)

Respondent emphasizes the fact that petitioner also reported pain in her neck (*Id.*) Though petitioner claims that her neck pain stems from a distinct injury, respondent argues that her medical records indicate that her neck pain was related to her left-hand paresthesia—prompting Dr. Cincere to order an EMG/NCS to evaluate petitioner for cervical radiculopathy. (*Id.*) Respondent also asserts that petitioner suffered from suprascapular neuropathy and cervical-spine pathology, either of which could explain her symptoms. (*Id.* at 7-8.) Suprascapular neuropathy causes shoulder pain, and respondent stresses that while this condition "may not explain all of petitioner's symptoms," respondent suggests that petitioner's theory that this neuropathy was "subclinical" is unconvincing. (*Id.*) Notably, respondent asserts that the QAIs specifically identify neuropathies as "conditions that preclude a Table SIRVA." (*Id.* (citing 42 C.F.R. § 100.3(b)(10)(iv)).) Furthermore, petitioner's cervical spine MRI showed disc desiccation at all levels, explaining the numbness and tingling that petitioner reported in her initial visit nine days post-vaccination. (ECF No. 51, p. 8.)

Respondent further contends that petitioner has not established causation in fact. (ECF No. 51, p. 8.) Under *Althen* prong one, respondent stresses that petitioner has not offered a persuasive medical theory linking the vaccination to her condition. (*Id.* at 9.) Respondent argues that prong one cannot be met simply by pointing to the fact that SIRVA is a Table injury. (*Id.*) Likewise, respondent asserts that the only support for Dr. Natanzi's needle over-penetration theory are case reports—which are weak evidence of causation. (*Id.* at 10.) Under prong two, respondent contends that there is no logical sequence of cause and effect showing that the vaccination caused petitioner's injury where the record indicates that petitioner's symptoms cannot be attributed to the type of mechanical shoulder injury that Dr. Natanzi claims is caused by the vaccine (impingement, bursitis, or capsulitis). (*Id.* at 11.) Specifically, respondent's expert explains that the pain petitioner suffered in her neck and in her left hand are indicative of cervical radiculopathy. (*Id.*) Moreover, petitioner received no benefit from subacromial steroid injection—suggesting that inflammation was not the cause of her pain. (*Id.* at 11-12.) Finally, respondent stresses that none of petitioner's treating doctors attributed her condition to the vaccine. (*Id.* at 12.) In fact, petitioner's orthopedic surgeon indicated that "the initial process of how this all started does not seem to make a lot of sense to me." (*Id.* (citing Ex. 4, p. 3).) Respondent did not address prong three, a proximate temporal relationship between vaccination and injury. (*See* ECF No. 51, pp. 8-13.)

VI. Analysis

a. Petitioner's Table Injury claim

As explained above, the Vaccine Injury Table lists SIRVA as a compensable injury if it occurs within 48 hours of administration of a vaccine containing the influenza virus. § 300aa-14(a) as amended by 42 C.F.R. § 100.3(a). To be considered a Table "SIRVA," petitioner must show: (i) there is "no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection"; (ii) that "onset of pain occurred within the specified timeframe," i.e. within 48 hours; (iii) that "pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered"; and (iv) that "no other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)." 42 C.F.R. § 100.3(a); 42 C.F.R. § 100.3(c)(10).

In this case there is no dispute as to the first and second QAI SIRVA criteria. Respondent raises no argument in either his Rule 4 report or his response to petitioner's motion for a ruling on the record that petitioner had a prior history of shoulder dysfunction, or that petitioner's injury arose outside of the 48-hour timeframe identified by the Vaccine Injury Table. (ECF Nos. 26, 51.) My own review of the record

confirms these points. Based on the record as a whole, petitioner has preponderantly established that she suffered onset of *new* shoulder pain within 48 hours of the vaccination at issue in this case. Rather, respondent's defense against petitioner's Table Injury claim hinges on the third and fourth SIRVA QAI prongs. Respondent contends that petitioner's pain was not limited to the shoulder in which she received her vaccination and also that her condition is better explained by suprascapular neuropathy and cervical-spine pathology. (ECF No. 51, pp. 6-8.) In this case, respondent's arguments regarding these two prongs are closely related.

With regard to the third SIRVA criterion, "the gravamen of this requirement is to guard against compensating claims involving patterns of pain or reduced range of motion indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder." *Grossmann v. Secretary of Health & Human Services*, 18-13V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022) (citing *Werning v. Sec'y of Health & Human Servs.,* No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020) (finding that a petitioner satisfied the third SIRVA QIA criterion where there was a complaint of radiating pain, but the petitioner was "diagnosed and treated solely for pain and limited range of motion to her right shoulder.")) Relatedly, the fourth QAI SIRVA criteria requires petitioner to demonstrate that no other condition or abnormality is present that would explain her symptoms. Important to this case, the SIRVA QAI's specifically identify *evidence of* neuropathy and radiculopathy, rather than confirmed diagnoses, as conditions which preclude a Table SIRVA. 42 C.F.R. § 110.3(b)(10(iv) (petitioner must have "No other condition or abnormality that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)").

Here, petitioner voiced subjective complaints demonstrating that she experienced pain beyond the left shoulder, including numbness and tingling to her left arm and hand at the outset and later onset of neck pain. (Ex. 2, pp. 14, 18; Ex. 4, pp. 1, 4, 24; Ex. 5, pp. 11, 48, 73; Ex. 10, p. 1.) Additionally, her medical records include two separate and potentially confounding diagnoses – suprascapular neuropathy and cervical radiculopathy. For all the reasons discussed by the experts there are substantial questions surrounding both diagnoses; however, each is supported by at least some objective evidence. Petitioner's February 1, 2017, EMG showed evidence of left suprascapular neuropathy. (Ex. 4, pp. 24-25.) Suprascapular neuropathy was also among her surgical findings. (*Id.* at pp. 21-23.) Additionally, petitioner's cervical spine MRI showed mild right C4-C5 canal and foraminal stenosis and mild right and minimal left C5-C6 canal and foraminal stenosis.[16] (Ex. 4, pp. 19-20.) Numbness and tingling are hallmark symptoms associated with radiculopathy. (Evans, *supra,* at Ex. A.6, p.

[16] Spinal stenosis is "the narrowing of the vertebral canal, nerve root canals or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space" and symptoms are caused compression of the cauda equina and include "pain paresthesias, and neurogenic claudication." *Spinal stenosis,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=108389 (last accessed Apr. 27, 2022).

648; Caridi et. al., *supra,* at Ex. A.4, 266.) Cervical radiculopathy is caused by compression of a cervical nerve root, and depending on the location of that compression, patients experience varying patterns of pain, weakness, and absent reflexes. (Caridi et al., *supra,* at Ex. A.4.) C5 radiculopathy, in particular, is associated with pain "in the shoulder and radiates down the ventral arm to below the elbow."[17] (*Id.* at 266.) Dr. Natanzi stresses that these initial numbness and tingling symptoms were more likely than not related to petitioner's SIRVA injury. (Ex. 18, p. 8 ("Radiating pains associated with numbness and tingling are common findings in cases of SIRVA."); Ex. 20, p.2.) However, he also acknowledges that cervical radiculopathy can cause shoulder pain and upper limb paresthesia. (Ex. 20, pp. 1-2; Caridi et al., *supra,* at Ex. A.4, p. 266.) He also agrees that a sensory radiculopathy could be the source of radicular symptoms in light of a negative EMG. (*Id.*)

As discussed further below in the cause-in-fact context, petitioner continued to complain of shoulder pain and reduced range of motion throughout her course of treatment and showed objective shoulder pathology on MRI consistent with bursitis and rotator cuff tendinitis. (Ex. 4, p. 29; Ex. 21, pp 1-2.) Thus, it does not appear that petitioner's neurologic conditions wholly explain her presentation. However, there is still significant evidence suggesting that one or both of petitioner's diagnosed cervical radiculopathy and/or suprascapular neuropathy presented as comorbid conditions that contributed to petitioner's overall presentation, with the cervical radiculopathy further standing as likely explanation of additional symptoms of numbness and tingling that extended beyond the confines of petitioner's musculoskeletal injury to her left shoulder. Petitioner therefore has not satisfied either the third or fourth SIRVA QAI criteria. Even if it is possible that petitioner's numbness and tingling might alternatively be explained by her shoulder pathology as Dr. Natanzi suggests, this evidence is enough to deprive petitioner of a causal presumption and require that petitioner's claim be assessed on a cause-in-fact basis.

b. Petitioner's Cause-in-Fact Claim

i. Medical theory causally connecting the vaccination and the injury (*Althen* prong one)

The first *Althen* prong requires petitioner to present a persuasive medical theory of causation demonstrating that the influenza vaccine could have caused her alleged

[17] Cervical radiculopathy was not seen on two different EMG procedures, on February 1, 2017 (Ex. 4, p. 24) and on July 19, 2017 (Ex. 4, p. 13). However, Dr. Abrams explains that patients with normal EMGs with known cervical pathology can demonstrate pain patterns in the neck and upper extremity. (Ex. C, p. 2.) Lazaro et al. studied 75 patients who had MRI confirmed spinal degermation, bulging discs, and facet hypertrophy with neck and upper extremity pain (with non-dermatomal paresthesias) who had normal EMG studies. (Lazaro et al., *supra,* at Ex. C.1.) The authors concluded that the utility of the EMG procedure is limited to pathology in the motor unit and "cannot assess the function of the sensory components of the spinal roots, small-diameter sensory nerves, and the sensory innervation of the spine via sinuvertebral nerve," strongly suggesting that a normal EMG does not rule out the presence of cervical spine mediated pain patterns. (*Id.* at 1.)

shoulder injury. *Althen,* 418 F.3d at 1278. It is well-established in the Vaccine Program that compensation may be awarded for shoulder injuries on a cause-in-fact basis. *See, e.g.*, *A.P. v. Sec'y of Health & Human Servs.,* No. 17-784V, 2022 WL 275785 (Fed. Cl. Spec. Mstr. Jan. 31, 2022); *L.J. v. Sec'y of Health & Human Servs.,* No. 17-0059V, 2021 WL 6845593 (Fed. Cl. Spec. Mstr. Dec. 2, 2021); *Tenneson v. Sec'y of Health & Human Servs.*, No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018) *rev. den.*, 142 Fed. Cl. 329 (2019). However, petitioner's medical theory must be supported by "reputable" scientific evidence and must "pertain[] specifically to the petitioner's case." *Moberly,* 592 F.3d at 1322.

In her motion petitioner asks this Court to take judicial notice that SIRVA was added to the Vaccine Injury Table for the influenza vaccine effective March 21, 2017. (ECF No. 49, p. 15.) However, where a petitioner alleges both an on-Table SIRVA and off-Table shoulder injury, she must set forth a theory of causation to meet her burden for the off-Table claim. *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992) (explaining with respect to cause-in-fact claims that "[s]imple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner."). "The Act relaxes proof of causation for injuries satisfying the Table in § 300aa–14, but does not relax proof of causation in fact for non-Table injuries." *Id.* at 1148. The government's recognition of "SIRVA" as a vaccine-caused injury was limited by the accompanying QAI criteria and for the reasons discussed above, I have already concluded that petitioner has not met those criteria.

Importantly, however, petitioner's expert cites three key articles concerning shoulder dysfunction post-vaccination.[18] (Ex. 18, p. 10.) Atanasoff et al., and Bodor and Montalvo were both cited as support for the addition of SIRVA to the Vaccine Injury Table. Proposed Rulemaking, 2015 WL 4538923, at *45136 (citing Atanasoff et al., *supra,* at Ex. 18.5; Bodor & Montalvo, *supra,* at Ex. 18.2). As petitioner posits, the mechanism set forth in Atanasoff is described as "the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." (ECF No. 49, p. 15; Atanasoff et al., *supra,* at Ex. 18.5, p. 8049.) This results in an inflammatory response which may be prolonged due to pre-existing antibody in the synovial tissue from an earlier, naturally occurring infection or vaccination. (*Id.* at 8051.) Atanasoff et al. further observed that bursitis and greater fluid in the bursa were two of the findings often seen in MRI studies of vaccine injured shoulders. (*Id.* at 8050.) The authors speculated that the patients they studied may have had prior conditions such as rotator cuff tears which only became symptomatic following the improper vaccine injection. (*Id.* at 8051.) Notably, Atanasoff et al. distinguished vaccine-related shoulder injuries from conditions caused by a mechanical injury or overuse by "the rapid onset of pain with limited range of motion following vaccination." (*Id.*) Arias et al., lent additional support for this proposed mechanism in a large systematic review, with a majority of

[18] Dr. Natanzi additionally cites Trollmo et al., a study addressing immune reaction without specific reference to SIRVA or SIRVA-like presentations, as well the study conducted by Cook, which sought to develop a specific protocol for the safe intramuscular vaccination of the deltoid muscle in adults. (Trollmo et al., *supra,* at Ex. 18.1; Cook, *supra,* at Ex. 18.4.)

cases reporting pain within 48 hours, and many reporting a high injection location. (Arias et al., *supra,* at Ex. 18.10.)

This medical literature provides preponderant evidence supporting the conclusion that the influenza vaccine can, when administered intramuscularly, cause an inflammatory response resulting in shoulder injury.

ii. Logical sequence of cause and effect showing that the vaccination was the reason for the injury (*Althen* prong 2)

The second *Althen* prong requires proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1375–77 (Fed. Cir. 2009); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant,* 956 F.2d at 1148. However, medical records and/or statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* 42 U.S.C. §300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

As previously noted, relative to the Table claim, prior to her November 2, 2016, vaccination petitioner had no prior history of pain or dysfunction in her upper left extremity or left shoulder. (Ex. 2, pp. 22-34; Ex. 11, p. 1-12.) Respondent raises no argument in either his Rule 4 report or his response to petitioner's motion for a ruling on the record to the contrary. (ECF Nos. 26; 51.) My own review of the record confirms these points.

Petitioner's presentation to Dr. Regan nine-days post-vaccination is strong evidence in support of a logical sequence of cause and effect showing that petitioner's shoulder injury was caused by her influenza vaccination. The history of present illness from that visit indicates that:

> [Petitioner] got a F[l]u shot last week on 11/02 an[d] her arm was red an[d] swollen and even warm to the touch an[d] they told her it was a bad reaction to the Flu VACC. [Petitioner] had flu vac 11/2/16 in the pm and was given supposedly im [intramuscular] but appears to have been given near the superior deltoid tendon…[B]y direct observation the injection site was to[o] far superior and not given IM.

(Ex. 2, p. 18.) An undated, handwritten note on petitioner's vaccine record reads "she had a severe reaction to flu shot – very sore arm (the shot site) – a week later reported CDC." (Ex. 1, p. 1.) In her affidavit petitioner described pain and swelling within thirty minutes after the vaccination. (Ex. 12, p. 1.)

Atanasoff et al. explain that the simple act of inserting a needle into the deltoid muscle would not be expected to cause an immune-mediated inflammatory response. (Atanasoff et al., *supra,* at Ex. 18.5, p. 8051.) Even when an individual is vaccinated in the deltoid muscle with a previously administered vaccine, "any local injection site reaction caused by vaccine-antigen antibody interaction is expected to be relatively brief and resolve as the antigen is clear from the soft tissues over a period of several days." (*Id.*) If, however, "a vaccine is injected into the synovial space of the shoulder (bursa or joint), pre-existing antibody in the synovial tissues…may lead to a more prolonged inflammatory response." (*Id.*) In "a great number of cases," Arias et al. found that "the vaccine had been administered into a 'very high site' in the arm, at a distance between 1 and 3 cm from the acromion." (Arias et al., *supra,* at Ex. 18.10, p. 4874.)

Dr. Regan's observation that petitioner's injection site was "to[o] far superior and not given IM [intramuscularly]" thus supports petitioner's theory that her influenza vaccination was injected into the synovial space of the shoulder, superior to the deltoid muscle.[19] (*Id.;* Ex. 2, p. 18.) Additionally, with regard to overpenetration, Dr. Zand's report traced the distance from the skin to the subacromial space (the path the needle would travel, according to petitioner's theory), and measured it to be between 18-20 millimeters. (Ex. 21, pp. 2, 7.) As Dr. Natanzi explains, a typical needle measures 25.4 mm, which is "plenty long enough to have caused penetration into the subacromial bursa and underlying rotator cuff." (Ex. 20, p. 3.)

There is some debate as to whether or not petitioner suffered from subacromial impingement bursitis and rotator cuff tendinitis. (Ex. 4, p. 21.) Dr. Abrams challenges Dr. Cincere's diagnoses based on Dr. Cincere's interpretation of petitioner's MRI and based on Dr. Cincere's operative findings from petitioner's left shoulder surgery. (Ex. C, p. 1.) However, the evidence preponderates in favoring of a finding that these conditions were present.

First, Dr. Abrams challenges petitioner's diagnosis of bursitis. Petitioner underwent a left-shoulder MRI on November 30, 2016. (Ex. 13.) The MRI report indicated (1) no evidence of rotator cuff tear, labral injury, or occult bone injury and (2) no abnormality in the subcutaneous or deltoid muscles surrounding the left humerus with "[n]o focal inflammatory process or free fluid." (*Id.*) Based on the radiologist's findings, Dr. Abrams opines that petitioner's MRI did not show any signs of bursitis. (Ex. C, p. 1.) However, petitioner's orthopedist, Dr. Cincere, reviewed her MRI on

[19] Dr. Abrams challenges the accuracy of Dr. Regan's observation of an incorrect vaccine location and argues that "the location of needle penetration to the skin would be difficult to visualize five [*sic*] days following vaccination." (Ex. C, p. 3.) For satisfying the second *Althen* prong, however, "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1280). Dr. Abrams may be correct that it is unlikely Dr. Regan would be able to confidently visualize the point of needle penetration himself. However, especially given that petitioner reported a reaction at the injection site itself, Dr. Regan's record is nonetheless in keeping with the taking of a careful history of present illness based on his in-person interaction with petitioner. This is exactly the type of issue for which contemporaneous treatment records are valued, given the accuracy warranted by the treatment context.

December 20, 2016, and "disagree[d] with [the] radiologist findings." (Ex. 14, p. 2.) Dr. Cincere noted "RTC [rotator cuff] signal changes: tendinosis, AC joint arthrosis, [and] bursal changes." (*Id*.) Dr. Abrams stresses that Dr. Cincere never specifically noted any inflammation or fluid in the bursa in his operative findings.[20] (Ex. C, p. 1; Ex. 4, pp. 22-23.) However, the first finding in Dr. Cincere's February 22, 2017, surgical report is "extensive subacromial bursitis." (Ex. 4, p. 21.) In his description of the procedure, Dr. Cincere observed "thick bursal tissue overlying the rotator cuff." (Ex. 4, p. 23.) Dr. Natanzi explains that this is expected for bursitis. (Ex. 20, p. 3.) Dr. Cincere further remarked that "the similar findings on the MRI were consistent with what was found with extensive bursitis" during petitioner's surgery. (Ex. 4, p. 23.) Dr. Zand, a diagnostic radiologist, additionally reviewed petitioner's MRI films and also agreed that petitioner's left shoulder revealed mild subacromial / subdeltoid bursitis. (Ex. 21, pp. 1-2.)

Second, Dr. Abrams challenges Dr. Cincere's diagnosis of rotator cuff tendinitis. Rotator cuff tendinitis is "an overuse injury consisting of inflammation of tendons of one or more of the muscles forming the rotator cuff[.]"[21] Dr. Abrams suggests that while many cases of SIRVA presented in the literature claim that needle over-penetration results in rotator cuff pathology, petitioner's bursal side of the rotator cuff was "completely intact," according to Dr. Cincere's operative report. (Ex. C, p. 1; Ex 4, p. 23.) In his operative report, Dr. Cincere identified "mild fraying" of the supraspinatus–one of the muscles that comprises the rotator cuff.[22] (Ex. 4, p. 22.) Additionally, Dr. Zand observed "moderate thickening and intermediate signal in the supraspinatus tendon *representing tendinosis*" in petitioner's MRI of her left shoulder. (Ex. 21, p. 1 (emphasis added).)

Overall, nothing in the record of this case calls into question Dr. Cincere's clinical care and, given his in-person treatment of petitioner and first-hand observation of her shoulder during surgery, he is better positioned than Dr. Abrams to make judgments as to the clinical significance of his own operative findings. *E.g*., *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show [s] that the vaccination was the reason for the injury'"); *see contra Schmidt v. Sec'y of Health & Human Servs.,* 17-1530V, 2021 WL 5226494 (Fed. Cl. Spec. Mstr. Oct. 7, 2021)(Chief special master finding Dr. Abrams

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[20] Bursitis is "inflammation of a bursa, occasionally accompanied by a calcific deposit in the underlying tendon" and "the most common site is the subdeltoid bursa." *Bursitis,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=7315&searchterm=bursitis (last accessed Apr. 13, 2022).

[21] *Rotator cuff tendinitis,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=112296&searchterm=rotator+cuff+tendinitis (last accessed Apr. 13, 2022).

[22] The rotator cuff is "a musculotendinous structure about the capsule of the shoulder joint, formed by the inserting fibers of the supraspinatus, infraspinatus, teres minor, and subscapularis muscles[.]" *Rotator cuff,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=67782&searchterm=rotator+cuff (last accessed Apr. 13, 2022).

persuasive where treating physician's affidavit was inconsistent with his own operative report showing no rotator cuff tear and MRI showing no bursal fluid). Although Dr. Cincere clearly felt petitioner had a complex history (*see, e.g.* Ex. 4, p. 3), it is also clear that he felt that history included shoulder pathology inclusive of bursitis.

In the cause-in-fact context, respondent also renews his argument that petitioner's symptoms cannot be attributed to the type of mechanical shoulder injuries discussed above. (ECF No. 51, p. 11.) Instead, respondent maintains that petitioner's pain in her left shoulder, neck, and left hand are indicative of cervical radiculopathy and suprascapular neuropathy. (*Id.* (Ex. A, pp. 4-5; Ex. C, pp. 1-2.)) Petitioner's presentation of symptoms and subsequent diagnoses complicate the matter; and a close look at the experts' reports and medical literature reveals why. As discussed above, petitioner has offered persuasive evidence in the medical records that she suffered some of the "classic" SIRVA injuries. (Arias et al., *supra,* at Ex. 18.10, p. 4873, Tab. 2; Ex. 4, p. 28; Ex. 14, pp. 17-19.) Impingement and bursitis could have likely caused petitioner's shoulder pain and limited range of motion. (Atanasoff et al., *supra,* at Ex. 18.5.) Separately, cervical radiculopathy could have likely caused the numbness and tingling in petitioner's left arm, hand, and fingers. (Caridi et al., *supra,* at Ex. A.4; Evans, *supra,* at Ex. A.6; Bogduk, *supra,* at Ex. A.3.)

However, Dr. Natanzi maintains that cervical radiculopathy was not the likely cause of petitioner's pain, for three reasons. (*Id.* at 2.) First, he stresses that petitioner never had any history of neck pain or upper limb symptoms prior to the date of vaccination. (*Id.*) For symptoms of a neck disorder (cervical radiculopathy) to have surfaced spontaneously after five decades of life, and coincidentally days after a shoulder injection (that can independently explain petitioner's symptoms), is very unlikely—Dr. Natanzi explains. (*Id.*) Second, multiple physical exams demonstrate signs of impingement and a restricted shoulder range of motion, which are indicative of a shoulder pathology, and would not be expected in the context of a cervical issue like radiculopathy. (*Id.*) Lastly, Dr. Cincere emphasizes the fact that an orthopedic surgeon performed surgery on the shoulder, and "[c]learly he would not have done so if he even suspected the pain was stemming from her neck." (Ex. 20, p. 2.)

Dr. Natanzi also opines that suprascapular neuropathy more than likely did not cause petitioner's shoulder pain because petitioner continued to experience clinical symptoms for more than two years after a normal NCS and surgical suprascapular nerve decompression. (Ex. 19, p. 2; Ex. 4, p. 13.) Dr. Abrams argues that if petitioner's numbness and tingling were a radiating symptom of her impingement syndrome or bursitis, petitioner would have likely shown post-operative improvement in her symptoms, or at least some clinical improvement with the anti-inflammatory injections. (Ex. A, p. 6; (citing Bodor et al., *supra,* at Ex. 18.2 (reporting both cases of SIRVA had complete pain relief after subacromial bursa-directed corticosteroid injections)).) Petitioner did demonstrate improvement, albeit inconsistently, following surgery. During her March 3, 2017, post-operative appointment, petitioner reported that "she goes to PT twice a week and noticed improvement." (Ex. 4, p. 31.) During a May 18, 2017, visit

with Dr. Cincere petitioner "voice[d] improvement with her therapy" and "state[d] the swelling [] decreased greatly." (Ex. 4, pp. 6-7.)

As the SIRVA medical literature indicates, orthopedic surgery is not a guaranteed remedy, and some patients suffer residual pain and limited joint movement for years. (Cross, *supra,* at Ex. 19.1, p. 305; Atanasoff, *supra,* at Ex. 18.5, p. 8050.) Ultimately, petitioner's MRI and multiple physical exams preponderantly demonstrate signs of bursitis, tendinitis, and restricted shoulder range of motion, which are indicative of a shoulder pathology and would not be expected in the context cervical radiculopathy and suprascapular neuropathy. (*See infra.*) Thus, petitioner's diagnoses of cervical radiculopathy and suprascapular neuropathy do not wholly explain petitioner's condition and do not preclude a finding that petitioner's November 2, 2016, influenza vaccination more likely than not caused her to suffer shoulder dysfunction, especially in light of her initial post-vaccination presentation. Therefore, petitioner has satisfied her burden under *Althen* prong 2.

iii. Proximate temporal relationship between vaccination and injury (*Althen* prong 3)

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Respondent raises no argument in either his Rule 4 report or his response to petitioner's motion for a ruling on the record that petitioner's injury arose outside of the 48-hour timeframe identified by the Vaccine Injury Table. (ECF Nos. 26, 51.) Nor does Respondent contest that the medically accepted timeframe for the onset of a shoulder injury caused-in-fact by vaccination is within 48 hours of vaccination. (*Id.*) Additionally, the Atanasoff study relied upon by petitioner supports 48 hours as the relevant onset period. In that study, 12 subjects (92% of the study population) experienced their symptoms within 48 hours of injection. (Atanasoff et al., *supra,* at Ex. 18.5, p. 8050.)

My own review of petitioner's medical records confirms that her symptoms began within 48 hours of vaccination. Petitioner presented to her primary care provider, Dr. Regan, nine days after receiving an influenza vaccination. She reported that her "arm was red and swollen and even warm to the touch and [that] they told her it was a bad reaction to the Flu VACC." (Ex. 2, p. 18.) Likewise, in her subsequent visits, petitioner continued to report shoulder pain and limited range of motion since receiving the influenza vaccination. (Ex. 14, pp. 2-3.) Petitioner's affidavit corroborates this account,

> When the pharmacist stuck the needle in my arm, I felt pain. Within 30 minutes the pain was so bad and my arm was swelling and I could not even

raise my arm. I have had the flu shot in the past so I was trying to think the best and hope it would get better with ice packs, however, it did not.

(Ex. 12, p. 1.)

Dr. Natanzi opines that, given the medical understanding of a shoulder injury related to vaccine administration, the onset of petitioner's left shoulder pain, beginning shortly after receipt of the influenza vaccination on November 2, 2016, it is medically acceptable to infer causation-in-fact. (Ex. 18, p. 7.) Accordingly, petitioner has preponderantly demonstrated that the onset of her left shoulder symptoms occurred within a time frame for which, given the medical understanding of shoulder dysfunction, it is medically acceptable to infer causation-in-fact.

iv. Factors Unrelated

Once petitioner has met her *prima facie* burden of demonstrating a Table Injury, respondent may still prove the condition is "due to factors unrelated to the administration of the vaccine described in the petition." § 300aa-13(a)(1)(B). However, while petitioner's comorbid diagnoses of suprascapular neuropathy and cervical radiculopathy may have caused some contributing neck pain and numbness and tingling, respondent has not shown, for the reasons detailed above, that these conditions explain petitioner's subacromial impingement bursitis and rotator cuff tendinopathy, identified on MRI and in Dr. Cincere's operative report. Thus, respondent cannot preponderantly establish under his shifted burden that these conditions wholly explain petitioner's alleged vaccine injury. Additionally, diagnoses of cervical spine radiculopathy and suprascapular neuropathy do not readily explain the specific circumstances of this case where petitioner experienced an abrupt onset of left shoulder pain within 48 hours of her November 2, 2016, influenza vaccination, nor do they explain the objective decrease in the range of motion of her left shoulder after vaccination that was not present previously. (Ex. 2, p. 18; Ex. 13; Ex. 14, p. 2; Ex. 4, pp. 21-23, 29.)

VII. Conclusion

For all the reasons discussed above, after weighing the evidence of record within the context of this Program, I find by preponderant evidence that petitioner suffered subacromial impingement bursitis and rotator cuff tendinitis caused-in-fact by her November 2, 2016, influenza vaccination. A separate damages order will be issued.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master